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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/706,965      | 11/06/2000  | Esmail Kiani-Azərbayjany | MLABS.018C3         | 8509             |

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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                                      |   |  |
|------------------------|--------------------------------------|---|--|
| <b>Advisory Action</b> | <b>Application No.</b><br>09/706,965 | <b>Applicant(s)</b><br>KIANI-AZARBAYJANY ET AL. |  |
|                        | <b>Examiner</b><br>Matthew J Kremer  | <b>Art Unit</b><br>3736                         |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 13 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Attached Arguments.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Attached Arguments.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1 and 12-24.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
**ERIC F. WINAKUR**  
PRIMARY EXAMINER

### **Advisory Action Attachment**

***2. The proposed amendments will not be entered because they raise new issues that would require further consideration and/or search.***

The Applicant contends that the amendments made to claims 17 and 23-24 do not raise new issues and should not require a new search because of the similarities to elements in non-amended claim 1. The Examiner respectfully disagrees. According to USPTO practice, each claim is to be examined individually according to the elements or steps listed in that particular claim. Any importation of a particular limitation of one independent claim, i.e., claim 1, into another independent claim, i.e., claims 17 and 23-24, does not necessarily mean the new list of limitations in the amended claims does not raise new issues. Claims 1, 17, and 23-24 are not identical and, therefore, have different scopes. The amendments to claim 17 and 23-24 include additional limitations (the "optical properties" and "the glucose concentration" limitations) that change the scope of these claims and, therefore, raise new issues requiring further search and consideration.

***3. The request for reconsideration has been considered but does not place the application in condition for allowance.***

First, the Applicant contends that Mendelson patent teaches and suggests only modulation through a physical clamp 26 placed at the measurement site. The Examiner respectfully disagrees since Mendelson specifically teaches that the "[m]odulation of

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blood volume...may be accomplished in a number of ways” which provides a teaching that the modulation is not just limited to the clamp but other methods may be employed. (column 4, lines 32-34 of Mendelson). Branstetter teaches a temperature element for increasing the blood flow that falls within the scope of the devices for creating blood flow modulation as suggested by Mendelson. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the temperature element of Branstetter for the pulse inducement device of Mendelson since Mendelson implies that other devices can be used to induce blood flow modulation and Branstetter teaches one such device. The Applicant’s contention that only clamp can be used is inconsistent with the teaching of the Mendelson reference.

Second, the Applicant contends the Branstetter teaches a heat source used to maintain tissue at a predetermined constant temperature, which is just the opposite of teaching or suggesting the modulation of temperature. The Applicant fails to understand the nature of the combination. Mendelson teaches that the blood flow is modulated, which means there is increasing and decreasing blood flow. (column 4, lines 31-34 of Mendelson). One example, as pointed out by the Applicant, is by applying variable pressure using a clamp. Branstetter teaches that varying the heating of tissue also modulates the blood flow. (column 2, lines 32-47 of Branstetter et al.). The Branstetter reference is used to teach a method of varying blood flow. One with ordinary skill in the art would understand that the heating is being varied to carry out the modulation as required by the combination and not at a constant temperature as argued by the Applicant.

Since the rejections of the independent claims are deemed proper due to the reasons stated above and the applicant provides no other arguments than the supposed deficiencies of the combination and the failure of the secondary references to teach those deficiencies, the rejection of the subsequent dependent claims are also maintained.

Third, the Applicant contends that Shiga teaches occlusion and this occlusion causes dramatic changed in the "optical properties at the test site." The Examiner would like to note that claim 1 states that the periodic changes in a volume of blood with "the level of inducement below a level that causes significant variations in the optical properties of the fleshy medium." This limitation was interpreted to mean that the optical properties of the flesh itself is not being varied, not the blood in the flesh. This interpretation is supported by the Applicant's own arguments dated on 1/8/2004 in which the Applicant argues against the Mendelson reference: "In contrast, the Mendelson reference fails to disclose any such minimal movement of the flesh in the test region. Movement of the fleshy medium in the test area can cause changes in the optical path length of the medium, resulting in optical scattering and other sources of noise that can distort the signals due to changes in fluid volume flow. The advantage of reducing this movement in the test area is that it correspondingly reduces the noise in the detected signal by isolating the variations due to varying fluid volume flow. Movement can be reduced by inducing the pulse at a location distal from the area receiving the incident light and by using gentle pressure." Shiga discloses a pulse oximeter probe that includes an active pulse inducement device 4 at a location other

than the test site (where fibers  $3_1$  and  $3_2$  are contacting the finger). (Fig. 5 of Shiga et al.). Such an arrangement reduces motion by inducing blood flow at a location separate from the area receiving the incident light.

In regard to claim 22, the Applicant was indeed correct that the Examiner intended to make a 103(a) rejection and the "102(b)" was a typographical error. But since the amendments to claim 17 would raise new issues, the dependent claim 22 would require further search and consideration.

In regard to claim 15, the Examiner was noting in the Final Rejection mailed on 3/16/2004 that claim 15 was rejected under 103(a) in view of the Mendelson-Branstetter combination and not under 102(e) as anticipated by Mendelson. The Applicant's arguments relating to claim 15 as rejected under Mendelson were not addressing the 103(a) rejection in view of the combination.